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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/276,935	03/26/1999	STEVEN A. KLIEWER	510-125	2851

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EXAMINER

PAK, MICHAEL D

ART UNIT PAPER NUMBER

1646

DATE MAILED: 07/29/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/276,935

Applicant(s)

Kliwer et al.

Examiner

Michael Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 22, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10 and 25-40 is/are pending in the application.
- 4a) Of the above, claim(s) 26, 36, and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10, 25, 27-35, and 37-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>23</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>21</u> | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Response to Amendment

1. The amendment filed on 29 January 2002 (Paper No. 18) has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant's arguments filed 29 January 2002 (Paper No. 18) have been fully considered but they are not found persuasive.
4. Newly submitted claims 26, 36, and 40 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:
 - X. Claim 26 drawn to a method of screening a compound in vivo, classification cannot be determined because the structure of the compound is not known.
 - XI. Claim 36 drawn to a method of screening a compound in vitro using solid support, classified in class 436, subclass 518.
 - XII. Claim 40 drawn to a method of selecting a drug compound which does not induce cytochrome P-450 gene expression, classified in class 435, subclass 7.8.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 26, 36, and 40 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 U.S.C. § 112

5. Claims 10, 25, 27-35 and 37-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recite the term "ligand binding domain of human pregnane X receptor having the amino acid sequence of SEQ ID NO:14" which is not clear because the metes and bounds of the term is not clear. The term "ligand binding domain" is recited in the claim without structural limitation, and is especially confusing in light of claim 27 which recites the protein comprising a specific amino acid sequence 141-434 of SEQ ID NO:14 and specification on page 7, lines 23-24, which state that the ligand binding domain has the amino acids 141-434 of figure 1 because the dependent claim 27 implies that claim 27 is further limiting claim 10 but claim 10 appears to be generic to claim 27. If the hPXR having the SEQ ID NO:14 has more than one ligand

binding domain then what is the metes and bounds of the ligand binding domain structurally. One skilled in the art would only assign one ligand binding domain for a hPXR receptor. Claims 25, 30-35, and 37-39 are dependent on claim 10 and encompass the term.

Claim 27 recite "amino acids 141-434 of SEQ ID NO:14" which is confusing because SEQ ID NO:14 only has 414 amino acids.

Claim 28 recite "amino acids 130-434 of SEQ ID NO:14" which is confusing because SEQ ID NO:14 only has 414 amino acids.

Claim 10 recite the term "CYP3A4 gene expression" which is not clear because the metes and bounds of the term is not clear. The term "CYP3A4 gene expression" is not clear because it is not clear what is the structural limitation of a "CYP3A4 gene expression". For example whether a direct repeat response elements of the DNA which is common in the "CYP3A4 gene expression" is sufficient to encompass the claim limitation. Applicants argue that CYP3A4 gene is expressed by transcription. However, it is not clear what is the metes and bounds of the structure of the CYP3A4 gene which is necessary for transcription and what is the structure of the gene being transcribed. Claims 25, 27-35, and 37-39 are dependent on claim 10 and encompass the term.

6. Claims 27 and 28 are rejected under 35 U.S.C. 112, first

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paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 27 and 28 recite claim limitation drawn to SEQ ID NO:14 with 434 amino acids which is new matter because SEQ ID NO:14 only has 414 amino acids.

7. No claim is allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Michael D. Pak
Michael D. Pak
Primary Patent Examiner
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23 July 2002